

### **REMARKS**

In the Office Action of October 13, 2010, the Examiner kindly identified, in detail, informalities in the Specification. Applicants are submitting herewith an amended first paragraph clearly identifying the relationship of the priority applications. Also submitted herewith is an amended Substitute Specification and a Substitute Specification with markings showing the amendments, which incorporate the amendments suggested by the Examiner.

The Examiner also kindly pointed out that the primer sequences used for amplifying genes according to the invention had not been assigned sequence identification numbers. These numbers have been assigned with this amendment to the Specification.

Claims 26, 27 and 33 have been objected to for informalities. These claims have been corrected in accord with the Examiner's suggestions.

Claim 13 stands rejected under 35 USC 101 for encompassing a naturally occurring *L. intracellularis*. Claim 13 is now directed to a host cell comprising a recombinant DNA molecule according to claim 11, which could not be a naturally occurring organism.

Claims 10-13, 25-28, 33 and 36 stand rejected under 35 USC 112, second paragraph, for being indefinite. The Examiner has objected that the phrase "stringent hybridization conditions" is vague and indefinite because hybridization conditions can vary considerably, and has suggested that the hybridization conditions be included in the claim.

With the present amendments, claims 25-28 no longer ultimately depend on claim 33, the claim referring to "stringent conditions." Claim 33 is now amended to

recite that the isolated nucleic acid that hybridizes has a mismatch of 10% or less, as set forth in the Specification on page 5, lines 23-25. In addition, the definition of “stringent conditions” for the purpose of this invention is set forth on page 5, lines 13-25. It includes a formula for  $T_m$ , the melting temperature of the hybridized nucleic acids, citing the source (Meinkoth and Wahl, Anal. Biochem, 138:267-284 (1984)). A copy of this publication is provided herewith.

Claims 29, 31, 25-28 and 36 stand rejected under 35 USC 112, second paragraph, for being indefinite. The Examiner has questioned the metes and bounds of “having the same immunological characteristics.”

The phrase “having the same immunological characteristics” has now been deleted, but without prejudice or disclaimer from pursuing claims with similar limitations in a related application.

With the present amendments claims 25-28 are ultimately dependent on new claim 41, which claims the isolated nucleic acid sequence of SEQ ID NO.: 1, and claim 29 depends on new claim 40, which claims the isolated protein of SEQ ID NO.: 2.

Claims 27 and 28 stand rejected under 35 USC 112, second paragraph, for being indefinite. The phrase “derived from” is objected to.

Claim 27 is now amended to recite that the additional antigen is “isolated from” another pathogen.

Claims 25-29, 38 and 39 stand rejected under 35 USC 112, first paragraph, for lack of enablement for vaccines of one subunit, or of subunits 27kD, 62kD, 57kD, 74kD, 43kD or 101kD.

With the present amendments, claims 25-28 depend on new claim 41, claiming the nucleic acid sequence of SEQ ID NO.: 1, and claim 29 depends on new claim 41,

claiming the isolated protein of SEQ ID NO.: 2. Claim 39 now claims a vaccine comprising the isolated 75 kD, 44 kD, 26/31 kD and 27 kD proteins.

Applicant submits herewith a Declaration under 37 CFR 1.132 presenting results of an experiment showing that a vaccine comprising the 75 kD protein [SEQ ID NO.: 2] as the *L. intracellularis* antigen is effective for inducing significant antibody titer, reducing shedding after challenge, significantly improving post-mortem scores of the llium, and resulting in negative histological scores after challenge. Support for a vaccine comprising a single identified antigen, as demonstrated in the experimental results now submitted, is supported in the Specification on page 2, lines 15-24.

In view of the above, with the present amendments, it is believed claims 10-13, 25-29 and 31-41 are in condition for allowance. Favorable action is solicited.

Applicant does not believe that any other fee is due in connection with this filing. If, however, Applicant does owe any such fee(s), the Commissioner is hereby authorized to charge the fee(s) to Deposit Account No. **19-0365**. In addition, if there is ever any other fee deficiency or overpayment under 37 C.F.R. §1.16 or 1.17 in connection with this patent application, the Commissioner is hereby authorized to charge such deficiency or repay such overpayment to Deposit Account No. **19-0365**.

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Amendment in Response to OA of 10/13/2010

Should the Examiner consider that a conference would be helpful in advancing the prosecution of this application, he is invited to telephone Applicant's attorney at the number below.

Respectfully submitted,

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